



Blue Cross of California

Rob Seidman, Pharm.D., M.P.H.
Vice President
Blue Cross of California Pharmacy

July 21, 1998

3760 '98 JUL 22 A9:36

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Rm. 1061
5630 Fishers Lane
Rockville, MD 20857

Dear Sir or Madam:

The undersigned submits this petition under the Code of Federal Regulations, Food and Drug Administration, Title-21, section 10.30. This regulation provides that drugs limited to prescription use under an NDA can be exempted from that limitation if the FDA determines the prescription requirements to be unnecessary for the protection of public health. By receipt of this letter, I am petitioning the FDA to make the following exemptions:

Currently, the Federal Food and Drug Administration (FDA) authorizes over 100 different antihistamine and antihistamine/decongestant combinations for over-the-counter (OTC) sale. Although considered safe and effective by the FDA, all OTC antihistamine and combination antihistamine/decongestant combinations are non-selective and have a more significant sedative and anticholinergic effect than the three leading prescription antihistamine and antihistamine/decongestant products. The safest antihistamine and antihistamine/decongestant combination medications are available only by a prescription and are described below:

Allegra (60 mg fexofenadine);

Allegra-D (60 mg fexofenadine, 120 mg pseudoephedrine);

Claritin (5 mg loratadine);

Claritin-D (5 mg loratadine, 120 mg pseudoephedrine);

Claritin-D 24 Hour (10 mg loratadine, 240 mg pseudoephedrine); and,

Zyrtec (5 mg cetirizine and 10 mg cetirizine strengths).

Maintaining Allegra/Allegra-D, Claritin/Claritin-D and Zyrtec as prescription drugs only, while their more dangerous antihistamine and antihistamine/decongestant alternatives are available without a prescription, deprives a majority of patients ready access to quality pharmaceutical care. This lack of access results in a greater incidence of side effects associated with the OTC alternatives adding considerable unnecessary medical costs to the health care system. The following information is provided to validate the petition and medical rationale for the conversion of Allegra/Allegra-D, Claritin/Claritin-D and Zyrtec to OTC status.

- Of the 3.5 billion health problems treated annually, almost 2 billion (or 57%) are treated with OTC drugs as primary or major adjunctive therapy. The current restrictions limiting OTC access to antihistamine and antihistamine/decongestant medications with a higher incidence of sedation and anticholinergic side effects is dangerous and costly.

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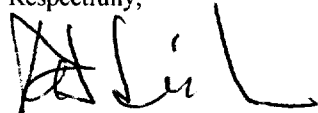
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- Americans are 4 times as likely to purchase an OTC medication as they are to consulting a physician. Many patients can not afford the office visit associated with a physician's visit. The current restrictions precluding OTC access to antihistamine and antihistamine/decongestant medications with a lower incidence of side effects predisposes many patients to dangerous antihistamine and antihistamine/decongestant treatment options.
- Almost 60% of all dosage units consumed by patients are for OTC medications. The current restrictions precluding OTC access to antihistamine and antihistamine/decongestant medications with a lower incidence of side effects limits many patients to dangerous antihistamine and antihistamine/decongestant treatment options.
- Over 500 medical conditions are treatable with one or more OTC medications as the primary therapy or major adjunctive therapy. These conditions occur millions of times each year (e.g. cold, allergy, and nasal congestion). The current restrictions precluding OTC access to antihistamine and antihistamine/decongestant medications with a lower incidence of side effects predisposes many patients to dangerous antihistamine and antihistamine/decongestant treatment options for the self treatment of many of these conditions.
- Requiring that a patient schedule an office visit to obtain safe medications such as Allegra/Allegra-D, Claritin/Claritin-D or Zyrtec is an undue time and financial burden to the patient. Additionally, requiring a prescription for these safe antihistamine and antihistamine/decongestant combinations trivializes the patient-physician relationship.
- Based on recent historical precedent, the cost of the OTC versions of the drugs listed above will be 50% of the prescription drug cost.

Patients are seeking greater ownership of their health care and often prefer to self medicate when feasible. Of all the therapeutic classes of drugs available, the discrepancy in safety between the antihistamine and antihistamine/decongestant combinations available OTC compared to prescription Allegra/Allegra-D, Claritin/Claritin-D and Zyrtec is most pronounced. Based on the information provided above, please expedite the conversion of Allegra/Allegra-D, Claritin/Claritin-D and Zyrtec to OTC medication status.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition

Respectfully,



Robert C. Seidman, PharmD, MPH
Vice President
Blue Cross of California Pharmacy

cc: Douglas Schur, Vice President of Legal Services



Blue Cross of California

Rob Seidman, Pharm.D., M.P.H.
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July 23, 1998

4178 '98 JUL 24 A9:27

G.D.

Food and Drug Administration
Division of Management Systems & Policy
Dockets Management Branch
ATTN: Gloria Ortega
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Dear Ms. Ortega:

Pursuant to Section 10.30, Section C of the Food and Drug Administration, we are requesting an exception to provide an environmental assessment under Section 25.24. Since the medications we are wishing to convert from prescription to over-the-counter (OTC) are already widely used, the conversion from prescription to OTC status will not result in the introduction of any additional drug substances into the environment. We appreciate your waiving of the environmental assessment provision for this important petition.

Respectfully,